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ELI LILLY AND COMPANY

By Lindan Dunbin

Date Manch 22, 2006

<u>PATENT APPLICATION</u> IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Richard Dennis DiMarchi, et al.)	
Serial No.	:	10/516,490)	
International Application Date	:	June 2, 2003)	Confirmation No.: 8626
For	:	Modified Glucagon-Like Peptide-1 Analogs	;)	
Docket No.	:	X-15642)	÷

STATEMENT TO SUPPORT FILING AND SUBMISSION IN ACCORDANCE WITH 37 C.F.R. 1.821(f) (SEQUENCE LISTING)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

I hereby affirm that the content of the paper and computer readable copies of the Sequence Listing, submitted in accordance with 37 C.F.R. 1.821(c) and (e), respectively, are the same.

Respectfully submitted,

Alejandro Martinez
Agent for Applicants
Registration No. 58,163

Phone: 317-277-4260

Eli Lilly and Company Patent Division P.O. Box 6288 Indianapolis, Indiana 46206-6288

Mark 22, 2006



STIC Biotechnology Systems Branch

RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: \(\frac{10/5/6,490A}{200} \)
Source: \(\frac{100}{100} \)
Date Processed by STIC: \(\frac{100}{100} \)

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 Alexandria, VA 22314

Revised 01/24/05





PCT

RAW SEQUENCE LISTING

DATE: 01/10/2006

PATENT APPLICATION: US/10/516,490A

TIME: 08:39:08

Input Set : A:\X15642.NatlPhase.ST25.txt
Output Set: N:\CRF4\01102006\J516490A.raw

```
3 <110> APPLICANT: Richard Dennis DiMarchi
             David Lee Smiley
             Lianshan Zhang
     7 <120> TITLE OF INVENTION: MODIFIED GLUCAGON-LIKE PEPTIDE-1 ANALOGS
     9 <130> FILE REFERENCE: X-15642 National Phase
                                                          M2-3,5-7
C--> 11 <140> CURRENT APPLICATION NUMBER: US/10/516,490A
C--> 11 <141> CURRENT FILING DATE: 2004-12-01
     11 <160> NUMBER OF SEQ ID NOS: 24
     13 <170> SOFTWARE: PatentIn version 3.2
     15 <210> SEQ ID NO: 1
    16 <211> LENGTH: 31
    17 <212> TYPE: PRT
                                                         Does Not Comply
    18 <213> ORGANISM: Artificial
                                                         Corrected Diskette Needed
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    21 <223> OTHER INFORMATION: Synthetic constructs
    24 <220> FEATURE:
    25 <221> NAME/KEY: MISC FEATURE
     26 <222> LOCATION: (1)..(1)
    27 <223> OTHER INFORMATION: Xaa= L-histidine, D-histidine, desamino-histidine,
             2-amino-histidine, beta-hydroxy-
     29
             histidine, homohistidine, alpha-fluoromethyl-histidine, or alpha
    30
            methyl-histidine
    32 <220> FEATURE:
    33 <221> NAME/KEY: MISC_FEATURE
    34 <222> LOCATION: (2)..(2)
     35 <223> OTHER INFORMATION: Xaa= Ala, Gly, Val, Leu, Ile, Ser, or Thr
    37 <220> FEATURE:
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    39 <222> LOCATION: (6)..(6)
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    44 <222> LOCATION: (10)..(10)
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    47 <220> FEATURE:
    48 <221> NAME/KEY: MISC_FEATURE
     49 <222> LOCATION: (12)..(12)
    50 <223> OTHER INFORMATION: Xaa= Ser, Trp, Tyr, Phe, Lys, Ile, Leu, Val
    52 <220> FEATURE:
    53 <221> NAME/KEY: MISC_FEATURE
    54 <222> LOCATION: (13)..(13)
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57 <220> FEATURE:

55 <223> OTHER INFORMATION: Xaa= Tyr, Trp, or Phe

Input Set : A:\X15642.NatlPhase.ST25.txt
Output Set: N:\CRF4\01102006\J516490A.raw

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     62 <220> FEATURE:
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     64 <222> LOCATION: (16)..(16).
     65 <223> OTHER INFORMATION: Xaa= Gly, Glu, Asp, Lys
     67 <220> FEATURE:
     68 <221> NAME/KEY: MISC FEATURE
     69 <222> LOCATION: (19) .. (19)
     70 <223> OTHER INFORMATION: Xaa= Ala, Val, Ile, or Leu
     72 <220> FEATURE:
     73 <221> NAME/KEY: MISC_FEATURE
     74 <222> LOCATION: (21)..(21)
     75 <223> OTHER INFORMATION: Xaa= Glu, Ile, or Ala
     77 <220> FEATURE:
     78 <221> NAME/KEY: MISC_FEATURE
     79 <222> LOCATION: (24)..(24)
     80 <223> OTHER INFORMATION: Xaa= Ala, or Glu
     82 <220> FEATURE:
     83 <221> NAME/KEY: MISC FEATURE
     84 <222> LOCATION: (27) .. (27)
     85 <223> OTHER INFORMATION: Xaa= Val, or Ile
     87 <220> FEATURE:
     88 <221> NAME/KEY: MISC_FEATURE ...
     89 <222> LOCATION: (31)..(31)
     90 <223> OTHER INFORMATION: Xaa= L-Cys, D-Cys, homocysteine, or penicillamine
     92 <400> SEQUENCE: 1
W--> 94 Xaa Xaa Glu Gly Thr Xaa Thr Ser Asp Xaa Ser Xaa Xaa Xaa Glu Xaa
                       5
                                            10
·W--> 98 Gln Ala Xaa Lys Xaa Phe Ile Xaa Trp Leu Xaa Lys Gly Arg Xaa
               20
                                        25
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     103 <211> LENGTH: 31
     104 <212> TYPE: PRT
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     114 <223> OTHER INFORMATION: Xaa= L-histidine, D-histidine, desamino-
histidine,
               2-amino-histidien, beta-hydroxy-
     115
     116
               histidine, homohistidine, alpha-fluoromethyl-histidine, or
               alpha-methyl-histidine
     119 <220> FEATURE:
     120 <221> NAME/KEY: MISC_FEATURE /
     121 <222> LOCATION: (2)..(2)
     122 <223> OTHER INFORMATION: Xaa= Gly, Ala, Val, Leu, Ile, Ser or Thr
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Input Set : A:\X15642.NatlPhase.ST25.txt
Output Set: N:\CRP4\01102006\J516490A.raw

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124 <220> FEATURE:
     125 <221> NAME/KEY: MISC_FEATURE
     126 <222> LOCATION: (10)..(10)
     127 <223> OTHER INFORMATION: Xaa = Val, Phe, Tyr, or Trp
     129 <220> FEATURE:
     130 <221> NAME/KEY: MISC FEATURE
     131 <222> LOCATION: (12)..(12)
     132 <223> OTHER INFORMATION: Xaa = Ser, Tyr, Trp, Phe, Lys, Ile, Leu, or Val
     134 <220> FEATURE:
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136 <222> LOCATION: (16)...(16)

137 <223> OTHER INFORMATION: Xaa = Gly, Clu Asp, or Lys

139 <220> FEATURE:
     140 <221> NAME/KEY: MISC FEATURE
     141 <222> LOCATION: (19) .. (19)
     142 <223> OTHER INFORMATION: Xaa = Ala, Val, Ile, or Leu
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     145 <221> NAME/KEY: MISC FEATURE
     146 <222> LOCATION: (27)..(27)
     147 <223> OTHER INFORMATION: Xaa = Val or Ile
     149 <220> FEATURE:
     150 <221> NAME/KEY: MISC FEATURE
     151 <222> LOCATION: (31)..(31)
     152 <223> OTHER INFORMATION: Xaa = L-Cys, D-Cys, homocysteine, or
penicillamine
     154 <400> SEOUENCE: 2
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                         5
                                               10
W--> 160 Gln Ala Xaa Lys Glu Phe Ile Ala Trp Leu Xaa Lys Gly Arg Xaa
                     20
                                         25
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     167 <213> ORGANISM: Artificial
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     175 <222> LOCATION: (1)..(1)
     176 <223> OTHER INFORMATION: Xaa = L-histidine, D-histidine, desamino-
histidine,
     177
               2-amino-histidine, beta-hydroxy-
     178
               histidine, homohistidine, alpha-fluoromethyl-histidine, or
     179
               alpha-methyl-histidine
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     182 <221> NAME/KEY: MISC FEATURE
     183 <222> LOCATION: (2)..(2)
     184 <223> OTHER INFORMATION: Xaa = Ala, Gly, Val, Leu, Ile, Ser, or Thr
     186 <220> FEATURE:
     187 <221> NAME/KEY: MISC FEATURE
     188 <222> LOCATION: (6) .. (6)
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Input Set : A:\X15642.NatlPhase.ST25.txt
Output Set: N:\CRF4\01102006\J516490A.raw

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189 <223> OTHER INFORMATION: Xaa = Phe, Trp, or Tyr
     191 <220> FEATURE:
     192 <221> NAME/KEY: MISC_FEATURE
     193 <222> LOCATION: (10)..(10)
     194 <223> OTHER INFORMATION: Xaa = Val, Trp, Ile, Leu, Phe, or Tyr
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     197 <221> NAME/KEY: MISC_FEATURE ...
     198 <222> LOCATION: (12)..(12)
     199 <223> OTHER INFORMATION: Xaa = Ser, Trp, Tyr, Phe, Lys, Ile, Leu, Val
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     203 <222> LOCATION: (13)..(13)
     204 <223> OTHER INFORMATION: Xaa = Tyr, Trp, or Phe
     206 <220> FEATURE:
     207 <221> NAME/KEY: MISC_FEATURE /
     208 <222> LOCATION: (14)..(14)
     209 <223> OTHER INFORMATION: Xaa = Leu, Phe, Tyr, or Trp
     211 <220> FEATURE:
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     214 <223> OTHER INFORMATION: Xaa = Gly, Glu, Asp, or Lys
     216 <220> FEATURE:
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     218 <222> LOCATION: (19)..(19)
     219 <223> OTHER INFORMATION: Xaa = Ala, Val, Ile, or Leu
     221 <220> FEATURE:
     222 <221> NAME/KEY: MISC_FEATURE
     223 <222> LOCATION: (21)..(21)
     224 <223> OTHER INFORMATION: Xaa = Glu, Ile, or Ala
     226 <220> FEATURE:
     227 <221> NAME/KEY: MISC FEATURE
     228 <222> LOCATION: (24)..(24)
     229 <223> OTHER INFORMATION: Xaa = Ala or Glu
     231 <220> FEATURE:
     232 <221> NAME/KEY: MISC FEATURE
     233 <222> LOCATION: (27)..(27)
     234 <223> OTHER INFORMATION: Xaa = Val or Ile
     236 <220> FEATURE:
     237 <221> NAME/KEY: MISC FEATURE
     238 <222> LOCATION: (28)..(28)
     239 <223> OTHER INFORMATION: Xaa = Lys, Asp, Arg, or Glu
     241 <220> FEATURE:
     242 <221> NAME/KEY: MISC FEATURE
     243 <222> LOCATION: (30)..(30)
     244 <223> OTHER INFORMATION: Xaa = Gly, Pro, or Arg
     246 <220> FEATURE:
     247 <221> NAME/KEY: MISC_FEATURE
     248 <222> LOCATION: (31)..(31)
     249 <223> OTHER INFORMATION: Xaa = Gly, Pro, Ser, L-Cys, D-Cys, homocysteine,
or penicillamine
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Input Set : A:\X15642.NatlPhase.ST25.txt
Output Set: N:\CRP4\01102006\J516490A.raw

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251 <220> FEATURE:
     252 <221> NAME/KEY: MISC_FEATURE.
     253 <222> LOCATION: (32)..(32)
     254 <223> OTHER INFORMATION: Xaa = Ser, Pro, His, L-Cys, D-Cys, homocysteine,
                    do you mean "amidation?" y so, please add "amidated
penicillamine,
     255
     257 <220> FEATURE:
     258 <221> NAME/KEY: MISC FEATURE
     259 <222> LOCATION: (33)..(33)
     260 <223> OTHER INFORMATION: Xaa = Ser, Arg, Thr, Trp, Lys, L-Cys, D-Cys,
homocysteine,
     261
               penicillamine, NH2
     262
               is absent
     264 <220> FEATURE:
     265 <221> NAME/KEY: MISC_FEATURE
     266 <222> LOCATION: (34)..(34)
     267 <223> OTHER INFORMATION: Xaa = Ser, Gly, L-Cys, D-Cys, homocysteine,
penicillamine, /NH2,
               or is absent
     268
     270 <220> FEATURE:
     271 <221> NAME/KEY: MISC FEATURE
     272 <222> LOCATION: (35)..(35)
     273 <223> OTHER INFORMATION: Xaa = Ala, Asp, Arg, Glu, Lys, Gly, L-Cys, D-Cys,
homocysteine,
     274
               penicillamine,
              (NH2) or is absent
     277 <220> FEATURE:
     278 <221> NAME/KEY: MISC FEATURE
     279 <222> LOCATION: (36)..(36)
     280 <223> OTHER INFORMATION: Xaa = Pro, Ala, L-Cys, D-Cys, homocysteine,
penicillamine, (NH2,)
               or is absent
     281
     283 <220> FEATURE:
     284 <221> NAME/KEY: MISC_FEATURE
     285 <222> LOCATION: (37)..(37)
     286 <223> ÆHER INFORMATION: Xaa = Pro, Ala, L-Cys, D-Cys, homocysteine,
penicillamine, (NH2) or
               is absent
     287
     289 <220> FEATURE:
     290 <221> NAME/KEY: MISC FEATURE
     291 <222> LOCATION: (38)..(38)/
     292 <223> OTHER INFORMATION: Xaa = Pro, Ala, Arg, Lys, His, L-Cys,
homocysteine,
     293
               penicillamine, (NH2) or
     294
               is absent
     296 <220> FEATURE:
     297 <221> NAME/KEY: MISC_FEATURE
     298 <222> LOCATION: (39)..(39)
     299 <223> OTHER INFORMATION: Xaa = Ser, His, Pro, Lys, Arg, L-Cys, D-Cys,
homocysteine,
     300
               penicillamine, NH2
     301
               is absent
     303 <220> FEATURE:
```

Page 6

304 <221> NAME/KEY: MISC_FEATURE
305 <222> LOCATION: (40)...(40)
homocysteine,
307

penicillamine, NH2 or

Please ersure that amero acids are spelled correctly in subsequent sequences.

RAW SEQUENCE LISTING ERROR SUMMARY PATENT APPLICATION: US/10/516,490A

DATE: 01/10/2006 TIME: 08:39:09

Input Set : A:\X15642.NatlPhase.ST25.txt
Output Set: N:\CRF4\01102006\J516490A.raw

Please Note:

Use of n and/or Xaa have been detected in the Sequence Listing. Please review the Sequence Listing to ensure that a corresponding explanation is presented in the <220>

to <223> fields of each sequence which presents at least one n or Xaa.

Seq#:1; Xaa Pos. 4,2,6,40,12,13,14,16,19,21,24,27,31 Seq#:2; Xaa Pos / X, 2/, 10, 12, 16, 19, 27, 31 Seq#:3; Xaa Pos . Y, 1/, 6, 10, 12, 13, 14, 16, 19, 21, 24, 27, 28, 30, 31, 32, 33, 34, 35, 36 Seq#:3; Xaa Pos. 37, 38,39,40,41,42 Seq#:4; Xaa Pos. 1,2,10,16,19,27,28,30,31,32,33,34,35,36,37,38,39,40,41,42 Seq#:5; Xaa Pos. 1,2,16,19,27,32,33,34,35,36,37,38,39,40,41,42 Seq#:6; Xaa Pos. 1,2,6,10,12,13,14,16,19,21,24,27,28,30,31,32,33,34,35,36 Seq#:6; Xaa Pos. 37,38,39,40,41,42,43,44,45 Seq#:7; Xaa Pos. 32,33,34,35,36,37,38,39,40,41,42,43,44,45 Seq#:8; Xaa Pos. 1,2,6,10,12,13,14,16,19,21,24,27 Seq#:9; Xaa Pos. 1,2,10,12,16,19,27 Seq#:10; Xaa Pos. 1,2,6,10,12,13,14,16,19,21,24,27,28,30,31,32,33,34,35,36 Seq#:10; Xaa Pos. 37,38,39,40,41,42 Seq#:11; Xaa Pos. 1,2,10,16,19,27,28,30,31,32,33,34,35,36,37,38,39,40,41,42 Seq#:12; Xaa Pos. 1,2,16,19,27,32,33,34,35,36,37,38,39,40,41,42 Seq#:13; Xaa Pos. 1,2,6,10,12,13,14,16,19,21,24,27,28,30,31,32,33,34,35,36 Seq#:13; Xaa Pos. 37,38,39,40,41,42,43,44,45 Seq#:14; Xaa Pos. 32,33,34,35,36,37,38,39,40,41,42,43,44,45 Seq#:15; Xaa Pos. 1,2,6,10,12,13,14,16,19,21,24,27,31

Invalid <213> Response:

Use of "Artificial" only as "<113> Organism" response is incomplete, per 1.823(b) of New Sequence Rules. Valid response is Artificial Sequence.

Seq#:1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22

VERIFICATION SUMMARY DATE: 01/10/2006 PATENT APPLICATION: US/10/516,490A TIME: 08:39:09

Input Set : A:\X15642.NatlPhase.ST25.txt
Output Set: N:\CRF4\01102006\J516490A.raw

L:11 M:270 C: Current Application Number differs, Replaced Current Application No L:11 M:271 C: Current Filing Date differs, Replaced Current Filing Date $L\!:\!94$ M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:1 after pos.:0 L:98 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:1 after pos.:16 L:156 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:2 after pos.:0 L:160 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:2 after pos.:16 L:324 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:3 after pos.:0 L:328 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:3 after pos.:16 L:332 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:3 after pos.:32 L:466 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:4 after pos.:0 L:470 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:4 after pos.:16 L:474 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:4 after pos.:32 L:583 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:5 after pos.:0 L:587 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:5 after pos.:16 L:591 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:5 after pos.:32 L:762 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:6 after pos.:0 L:766 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:6 after pos.:16 L:770 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:6 after pos.:32 L:869 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:7 after pos.:16 L:873 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:7 after pos.:32 L:951 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:8 after pos.:0 L:955 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:8 after pos.:16 L:1008 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:9 after pos.:0 L:1012 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:9 after pos.:16 L:1160 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:10 after pos.:0 L:1164 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:10 after pos.:16 L:1168 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:10 after pos.:32 L:1286 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:11 after pos.:0 L:1290 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:11 after pos.:16 L:1294 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:11 after pos.:32 L:1391 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:12 after pos.:0 L:1395 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:12 after pos.:16 L:1399 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:12 after pos.:32 L:1561 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:13 after pos.:0 L:1565 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:13 after pos.:16 L:1569 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:13 after pos.:32 L:1658 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:14 after pos.:16 L:1662 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:14 after pos.:32 L:1745 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:15 after pos.:0 L:1749 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:15 after pos.:16